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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/672,330	09/28/2000	Ken Zhang	S63.2-9176	7670

490 7590 04/14/2003

VIDAS, ARRETT & STEINKRAUS, P.A.
6109 BLUE CIRCLE DRIVE
SUITE 2000
MINNETONKA, MN 55343-9185

EXAMINER

FONTAINE, MONICA A

ART UNIT	PAPER NUMBER
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1732

DATE MAILED: 04/14/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/672,330

Applicant(s)

ZHANG ET AL.

Examiner

Monica A Fontaine

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) 13 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-13 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 28 September 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4,6.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claim 14 been renumbered to be claim 13.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, drawn to a process for producing a balloon, classified in class 264, subclass 529.
- II. Claim 13, drawn to a batch, classified in class 428, subclass 35.7The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product as claimed can be made by another and materially different process, such as one which does not contain an axial stretching step.

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During a telephone conversation with Walter Steinkraus on 9 April 2003 a provisional election was made with oral traverse to prosecute the invention of Group I, claims 1-12. Affirmation of this election must be made by applicant in replying to this Office action. Claim 13 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities: The status of the copending application on Page 2, line 4 should be updated.

Appropriate correction is required.

Claim Objections

Claim 1 is objected to because of the following informalities: "ID" should be changed to --internal diameter--. Appropriate correction is required.

Claims 1 and 6 are objected to because of the following informalities: The phrase "portion (A)" should be changed to --portion A-- since "A" is indentifying the portion.

Appropriate correction is required.

Claims 7-10 are objected to because of the following informalities: The phrases "portion (B1)" in claims 7-10 and "portion (B2)" in claims 9-10 should be changed to --portion B1-- and --portion B2--, respectively, since "B1" and "B2" are identifying specific portions. Appropriate correction is required.

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Claim 5 is objected to because of the following informalities: The examiner believes that the word "up" in line 2 is extraneous and should be deleted. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 8, and 10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the step (a)(i)" in line 8. There is insufficient antecedent basis for this limitation in the claim.

Claims 8 and 10 recite the limitation "the step (a)(ii)" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Jackowski et al. (U.S. Patent 5,017,325).

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Regarding Claim 1, Jackowski et al., hereafter “Jackowski,” show that it is known to carry out a process for producing a balloon comprising (a) axially stretching an extruded tubing segment made of a polymer material while pressurizing the tubing at an internal pressure above ambient pressure (Column 5, lines 25-27; Column 8, lines 32-37), to produce a stretched parison, the tubing segment having a first ID (Column 5, lines 44-46) and the polymer material having a glass transition temperature above ambient temperature (Column 13, lines 37-49), and then (b) blowing the balloon by expanding the stretched parison in a mold at a temperature above said glass transition temperature (Column 6, lines 35-40; Column 9, lines 67-68 – Column 10, lines 1-10), wherein said axially stretching comprises the step (a)(i) of subjecting the tubing to a temperature and internal pressure which is sufficient to expand the ID of at least a portion (A) of the stretched parison to a second ID greater than the first ID (Column 5, lines 54-62; Column 9, lines 67-68 – Column 10, lines 1-10).

Regarding Claims 2 and 3, Jackowski shows that it is known to carry out a process wherein the polymer material is a polyamide (Column 5, lines 14-15).

Regarding Claim 4, Jackowski shows that it is known to carry out a process wherein said extruded tubing segment is formed of a single layer of polymer material (Column 5, lines 25-27).

Regarding Claim 6, Jackowski shows that it is known to carry out a process wherein the balloon comprises a body portion having proximal and distal ends; proximal and distal cone portions, the cone portions being respectively located adjacent the respective proximal and distal ends of the balloon body; and proximal and distal waist portions adjacent the respective proximal and distal cone portions, and wherein, in step (b), said portion (A) of the stretched parison forms at least the balloon body (Figure 2c).

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Regarding Claim 7, Jackowski shows that it is known to carry out a process wherein the stretched parison comprises a second portion (B1) having an ID which is not greater than the first ID and in step (b) one of the waist portions of the balloon is formed from said portion (B1) (Figure 2c; Column 5, lines 44-46).

Regarding Claim 8, Jackowski shows that it is known to carry out a process wherein said axial stretching further comprises the step (a)(ii), of forming said stretched parison portion (B1) by reducing a portion of the extruded tubing segment to an ID less than said first ID prior to step (a)(i) (Column 5, lines 44-46, 54-62).

Regarding Claim 9, Jackowski shows that it is known to carry out a process wherein portion (B1) of the stretched parison forms the distal waist portion of the balloon, and the stretched parison comprises a third portion (B2) having an ID which is not greater than the first ID and in step (b) the proximal waist portion of the balloon is formed from said portion (B2) (Figure 2c).

Regarding Claim 10, Jackowski shows that it is known to carry out a process wherein said axial stretching further comprises the step (a)(ii), of forming at least one of said stretched parison portion (B1) and (B2) by necking down a portion of the extruded tubing segment to an ID less than the first ID (Figure 2c; Column 5, lines 44-46).

Regarding Claim 11, Jackowski shows that it is known to carry out a process wherein step (a)(ii) is performed at a pressure or temperature which is less than the pressure and temperature employed in step (a)(i) (Column 5, line 35; Column 6, lines 8-11; Column 9, lines 8-27).

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Regarding Claim 12, Jackowski shows that it is known to carry out a process wherein in step (a)(i) the pressure is 150-300 psi (Column 6, lines 35-40) and the temperature is 30°C-60°C (Column 10, lines 1-10).

Regarding Claim 13, Jackowski shows that it is known to carry out a process wherein a batch of balloons is produced by the process of claim 1 (Column 8, lines 21-26). Although Jackowski does not specify a number of balloons per batch, the significance of the claimed number of balloons per batch, 50, is unclear, as the instant application also contains examples drawn to batches of less than 50 balloons.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jackowski, in view of Hamlin (U.S. Patent 5,270,086). Jackowski shows the process as claimed as discussed above, but does not show forming a balloon with a multi-layer tube. Hamlin shows that it is known to form a balloon from an extruded tubing segment containing at least two layers of polymer material (Column 2, lines 1-2; Column 3, lines 9-16). Hamlin and Jackowski are combinable because they are concerned with a similar technical field, namely, that of molding balloons for medical devices. It would have been obvious to one of ordinary skill in the art at the time the

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invention was made to use Hamlin's multi-layer extruded tubing in Jackowski's molding process in order to increase the strength of the balloon (see Hamlin, Column 2, lines 2-11).

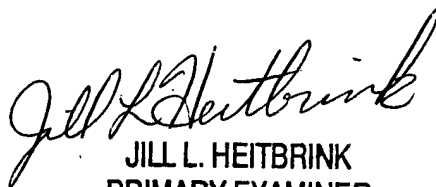
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Monica A Fontaine whose telephone number is 703-305-7239. The examiner can normally be reached on Monday-Friday 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rick Crispino can be reached on 703-308-3853. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9310 for regular communications and 703-872-9310 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.

maf
April 10, 2003


JILL L. HEITBRINK
PRIMARY EXAMINER
ART UNIT ~~137~~ 1732
4/11/03